Medicines Amendment Bill

Government Bill

Explanatory note

General policy statement

The purpose of this Bill is to amend the Medicines Act 1981 (the **principal Act**) to clarify the appropriate use of provisional consents to sell and use medicines, and ensure that New Zealanders continue to have timely access to safe and effective medicines.

The Bill meets these objectives by amending section 23 of the principal Act to allow the Minister of Health to give provisional consent for a medicine if the Minister is of the opinion that it is desirable that the medicine be sold, supplied, or used. The amendment removes the requirement for the sale, supply, or use to be for a limited number of patients. This is consistent with the policy intent that New Zealanders have access to safe and effective medicines where there is a public health need.

The amendment would enable the Minister to grant provisional consent for medicines where justified, due to an identified public health need and where limited information means that a full consent process (under section 20 of the principal Act) is not feasible.

The amendment does not affect existing requirements related to the safety, quality, and efficacy of the medicines and an assessment of the therapeutic benefits and risks, as set out in sections 21 and 22 of the principal Act.

The amendment does not affect the ability for conditions to be imposed on the use of the medicine (under section 23(3)(c) of the principal Act), where these are justified and consistent with the Minister's reasons for granting the provisional consent.

Provision is made in *new Schedule 1AA* for the validation of the provisional consent for the COVID-19 Pfizer vaccine, and the provisional consents for Necon 0.5/35 (tablets); 0.9% Sodium Chloride Injection (solution for infusion 0.9 %); Panvax vaccine (suspension for injection, 30 mcg/0.5mL, pandemic influenza vaccine); Brevinor 28

Day (tablet, Australian stock); and H5N1 Influenza Vaccine (suspension for injection 30 mcg/0.5mL, Seqirus).

Departmental disclosure statement

The Ministry of Health is required to prepare a disclosure statement to assist with the scrutiny of this Bill. The disclosure statement provides access to information about the policy development of the Bill and identifies any significant or unusual legislative features of the Bill.

A copy of the statement can be found at http://legislation.govt.nz/disclosure.aspx?type=bill&subtype=government&year=2021&no=41

Regulatory impact statement

A regulatory impact statement is not required for this Bill.

Clause by clause analysis

Clause 1 is the Title clause.

Clause 2 states that this Bill comes into force on the day after the date on which it receives the Royal assent.

Clause 3 states that this Bill amends the Medicines Act 1981.

Part 1: Amendment to provisional consenting provision

Clause 4 amends section 23 of the principal Act so that the Minister may give a provisional consent for a medicine if the Minister is of the opinion that it is desirable that the medicine be sold, supplied, or used. This replaces the requirement for the Minister to be of the opinion that it is desirable that the medicine be sold, supplied, or used on a restricted basis for the treatment of a limited number of patients.

This amendment does not affect the 2-year time limit on provisional consents that is set out in section 23(4) of the principal Act. Nor does it affect the requirement for the Minister to determine an application for provisional consent in accordance with section 22 of the principal Act. Under section 22(1), the Minister must—

- consider all of the particulars and information relating to the medicine that must be submitted with the application, and such other matters as appear to the Minister to be relevant; and
- as far as practicable, weigh the likely therapeutic value of the medicine against the risk (if any) of the use of the medicine injuriously affecting the health of any person.

Section 22 also sets out a process for referring applications to an advisory or technical committee established under the principal Act and, potentially, to the Medicines Review Committee.

Part 2: Validations

Clause 5 inserts *new section 5C* into the principal Act. The new section gives effect to transitional, savings, and related provisions set out in *new Schedule 1AA*.

Clause 6 inserts *new Schedule 1AA* into the principal Act.

Clause 1 of new Schedule 1AA states that the provisional consents for Comirnaty (COVID-19 mRNA vaccine) (also known as the Pfizer vaccine) and certain other medicines must be treated as if they were given under section 23 of the principal Act as amended by this Bill. The effect of *clause 1* is to validate those provisional consents to the extent that there may be a question about whether the medicines are intended to be sold, supplied, or used for the treatment of a limited number of patients.

Hon Andrew Little

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Contents

The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Medicines Amendment Act **2021**.

2 Commencement

This Act comes into force on the day after the date on which it receives the Royal assent.

3 Principal Act

This Act amends the Medicines Act 1981.

Part 1
Amendment to provisional consenting provision

4 Section 23 amended (Minister may give provisional consent)

Replace section 23(1) with:

(1) Notwithstanding sections 20 to 22, the Minister may, by notice in the *Gazette*, in accordance with this section, give provisional consent to the sale or supply or use of a new medicine if the Minister is of the opinion that it is desirable that the medicine be sold, supplied, or used.

Part 2
Validations

5 New section 5C inserted (Transitional, savings, and related provisions)

After section 5B, insert:

5C Transitional, savings, and related provisions

The transitional, savings, and related provisions set out in **Schedule 1AA** have effect according to their terms.

6 New Schedule 1AA inserted

Insert the **Schedule 1AA** set out in the **Schedule** of this Act as the first schedule to appear after the last section of the principal Act.

Schedule
New Schedule 1AA inserted

s 6

Schedule 1AA
Transitional, savings, and related provisions

s 5C

Part 1
Provisions relating to Medicines Amendment Act 2021

1 Validation of certain provisional consents

(1) The following provisional consents must be treated as having been given under section 23 as amended by the Medicines Amendment Act **2021**:

(a) the provisional consent for Comirnaty (COVID-19 mRNA vaccine) (as notified in Provisional Consent to the Distribution of a New Medicine (*Gazette* 2021-go338)):

(b) the provisional consent for Necon 0.5/35 (as notified in Provisional Consent to the Distribution of a New Medicine (*Gazette* 2020-go2377)):

(c) the provisional consent for 0.9% Sodium Chloride Injection (as notified in Provisional Consent to the Distribution of a New Medicine (*Gazette* 2020-go3009)):

(d) the provisional consent for the Panvax vaccine (as notified in Provisional Consent to the Distribution of a New Medicine (*Gazette* 2018-go6374)):

(e) the provisional consent for Brevinor 28 Day (as notified in Provisional Consent to the Distribution of New Medicines (*Gazette* 2020-go1987)):

(f) the provisional consent for H5N1 Influenza Vaccine (as notified in Provisional Consent to the Distribution of New Medicines (*Gazette* 2018-go576)).

(2) For the purposes of **subclause (1)**,—

(a) the Medicines Amendment Act **2021** must be treated as having been in force when the provisional consents were given; and

(b) a reference to a provisional consent includes any renewal of the provisional consent or subsequent provisional consent for the same product; and

(c) a reference to a notice in the *Gazette* includes any notice that amends or replaces that notice.

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